

## CLAIMS

1 1. A valve assembly adapted to be positioned into a urethra in a mammal, including humans, the  
2 valve assembly comprising a) a valve holder comprising a substantially cylindrically shaped  
3 body to be inserted into the urethra and b) a valve housing comprising a valve controlling an  
4 urine flow from a patients bladder, the valve assembly being 'arranged in a sealed manner  
5 between the walls of the urethra, characterised in  
6 that the cylindrical valve holder (1) comprise a shape memory alloy to provide an expandable  
7 element having the possibility to expand after the insertion of said valve holder (1) to increase its  
8 diameter at its upper end (2) to provide a frustoconical portion, whereby the increase of the  
9 diameter of the cylinder at its upper end is more than 15 % and whereby the increase of the  
10 diameter of said cylindrical valve holder (1) is temperature dependent.

1 2. Valve assembly according to claim 1,  
2 characterised in  
3 that the cylindrical valve holder (1) increase its diameter at its lower end (2).

1 3. Valve assembly according to claim 1-2,  
2 characterised in  
3 that the valve holder (1) comprises at least two frustoconically shaped portions (2, 2).

1 4. Valve assembly according to claims 2-3,  
2 characterised in  
3 that the valve holder (1) comprises at least two frustoconically shaped portions at one end of the  
4 cylinder.

1 5. Valve assembly according to claims 1-4,  
2 characterised in  
3 that the valve holder (1) comprises at least two frustoconically shaped portions at one end of the  
4 cylinder as well as at least one frustoconically shaped portion at the opposite end thereof.

1 6. Valve holder according to claims 1-5,  
2 characterised in

3 that the holder (1) and the housing (3) are detachable from each other when in place in the  
4 urethra.

1 7. Valve assembly according to claims 1-5, characterised in that the holder (1) and the housing  
2 (3) are detachable from each other.

1 8. Valve assembly according to claim 1,  
2 characterised in  
3 that the valve holder (1) includes a first portion (2) exhibiting a frustoconical shape, a second  
4 portion being essentially cylindrical and a third portion (2) exhibiting a frustoconical shape  
5 directed in opposite direction in relation to the first portion.

1 9. Valve assembly according to claim 1,  
2 characterised in  
3 that the valve holder (1) includes a first portion exhibiting at least two parts having frustoconical  
4 shape, a second portion being essentially cylindrical and a third portion exhibiting a frustoconical  
5 shape directed in opposite direction in relation to the first portion.

1 10. Valve assembly according to claims 1-8,  
2 characterised in  
3 that the holder (1) is helix shaped wire arranged onto the valve housing.

1 11. Valve assembly according to claims 1-9,  
2 characterised in  
3 that the holder (1) comprise a helix shaped wire threaded on external threads arranged on the  
4 outside of the valve housing.

1 12. Valve assembly according to claims 1-10,  
2 characterised in  
3 that the increase of the diameter of the helix shaped wire at its upper end is more than 15 %.

1 13. Valve assembly according to claim 11,  
2 characterised in

- 3 that the increase of the diameter of the cylinder at its upper end is at least 40 %.
- 1 14. Valve assembly according to claims 1-10,  
2 characterised in  
3 that the increase of the diameter of the helix shaped wire at its upper end is at least 40 %.
- 1 15. Valve assembly according to claims 1-14,  
2 characterised in  
3 that the increase of the diameter of the helix shaped wire at its upper end after expansion is at  
4 least 25 %.
- 1 16. Valve assembly according to claims 1-15,  
2 characterised in  
3 that the increase of the diameter of the helix shaped wire at its lower add is at least 10 %.
- 1 17. Valve assembly according to claims 1-16,  
2 characterised in  
3 that the increase of the diameter of the helix shaped wire at its lower end after expansion is at  
4 least 20 %.
- 1 18. Valve assembly according to claims 1-17,  
2 characterised in  
3 that the increase of the diameter of the cylindrical portion of the valve holder is less than 80 %.
- 1 19. Valve assembly according to claims 1-18,  
2 characterised in  
3 that said valve holder comprise an expandable element having the possibility to shrink upon  
4 removal of said valve housing.
- 1 20. Valve assembly according to claim 1,  
2 characterised in  
3 that the total length of the assembly is less than the length of the female urethra where it is  
4 intended to be inserted.

- 1 21. Valve assembly according to claim 1,  
2 characterised in  
3 that the total length of the valve is less than 60 mm.
- 1 22. Valve assembly according to claims 1-21,  
2 characterised in  
3 that the total length of the valve assembly is between 5 and 40 mm, preferably 5-30 mm.
- 1 23. Valve assembly according to any of claims 1-22,  
2 characterised in  
3 that at least a part of the length of the valve body of said valve assembly has a bending stiffness  
4 higher than  $0.0004 \text{ Nm}^2$  (Newton square meter).
- 1 24. Valve assembly according to any of claims 1-23,  
2 characterised in  
3 that at least a part of the length of the valve body of said valve assembly has a bending stiffness  
4 higher than  $0.0004 \text{ Nm}^2$  (Newton square meter) and that at least a part of the length of the valve  
5 body of said valve assembly has a bending stiffness lower than  $0.05 \text{ Nm}^2$  (Newton square meter).
- 1 25. Valve assembly according to any of claims 1-24,  
2 characterised in  
3 that the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton  
4 square meter) is less than 80% of the length of the female urethra where it is intended to be  
5 inserted.
- 1 26. Valve assembly according to any of claims 1-25,  
2 characterised in  
3 that the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton  
4 square meter) is less than 50mm.
- 1 27. Valve assembly according to any of claims 1-26,  
2 characterised in  
3 that the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton

4 square meter) is less than 40mm.

1 28. Valve assembly according to any of claims 1-27,  
2 characterised in  
3 that the part of the valve assembly with bending stiffness higher than  $0.0004 \text{ Nm}^2$  (Newton  
4 square meter) is between 5 and 60 mm.

1 29. A valve adapted to be positioned into a urethra and in a valve assembly according to claims  
2 1-28, said valve for emptying a patient's urine collected within his bladder, comprising:  
3 a tubular vane housing having an upper, lower, and central part and a channel therein; -  
4 a valve body situated at the lower part of the housing a valve seat situated below said valve body,  
5 said central part having at least one drainage hole extending through said tubular housing, said  
6 drainage hole located in the area between the upper end and the valve seat, said channel of the  
7 valve housing in communication with said drainage hole, said valve body being arranged to be  
8 moved in a longitudinal characterised in  
9 that the total length of the valve is less than 60 mm.

1 30. A valve adapted to be positioned into a urethra and in a valve assembly according to claims  
2 1-29, said valve for emptying a patient's urine collected within his bladder, comprising:  
3 a tubular valve housing having an upper, lower, and central part and a channel therein;  
4 a valve body situated at the lower end of the housing and attached to a valve rod which in an  
5 opposite end thereof comprises a magnet accommodated in the upper portion of the valve;  
6 a valve seat situated below said valve body,  
7 said central part having at least one drainage hole extending through said tubular housing, said  
8 drainage hole located in the area between the upper part and the valve seat, said channel of the  
9 valve housing in communication with said drainage hole, said valve body being arranged to be  
10 moved in a longitudinal direction by means of a part of the valve rod extending below said valve  
11 rod.

1 31. Valve according to one or more of the preceding claims,  
2 characterised in  
3 that the valve housing comprises a magnetic controlled valve.

1 32. Valve according to one or more of the preceding claims,  
2 characterised in  
3 that the valve is electro-magnetically controlled.

1 33. Valve according to one or more of the preceding claims,  
2 characterised in  
3 that the valve is mechanically controlled.

1 34. Valve according to one or more of the preceding claims,  
2 characterised in  
3 that the valve is electro-magnetically or mechanically controlled independent of the pressure in  
4 the bladder to be emptied.

1 35. Valve according to one or more of the preceding claims  
2 characterised in  
3 that the valve may be opened by means of a opening force being between 10 to 200 mN.

1 36. Valve according to claim 35,  
2 characterised in  
3 that the valve may be opened by means of a opening force being between 20 to 100 mN.

1 37. Valve according to claims 30-36  
2 characterised in  
3 that the valve is partly flexible, and partly rigid, whereby the rigid part is shorter than 50 mm.

1 38. Method for emptying a patient's urine bladder, whereby a valve assembly in accordance with  
2 claims 1-37 is inserted in the urethra and influenced at time intervals to open and empty said  
3 bladder.